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Docket No.: NAG-10002/50
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Ivo Volpato et al.

Application No.: 10/518,106

Confirmation No.: 5318

Filed: December 10, 2004

Art Unit: 1723

For: NEW INDUSTRIAL PROCESS FOR FOOD
LIQUIDS DECONTAMINATION FROM
CHEMICAL AND/OR BIOLOGICAL
CONTAMINANTS

Examiner: Joseph Drodge

AMENDMENT IN RESPONSE TO FINAL OFFICE ACTION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

INTRODUCTORY COMMENTS

In response to the office action dated May 12, 2008, please amend the above-identified U.S. patent application as follows:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 5 of this paper.

AMENDMENTS TO THE CLAIMS

Please cancel Claims 1-26.

27. (Currently Amended) Process for decontaminating a liquid food from one or more chemical and/or biological contaminants wherein one or more biocompatible polymer membranes to which antibodies specific for said contaminants are chemically conjugated through a linker, are immersed into said liquid, said one or more membranes being free to move in the liquid and being kept taut by floats at one end and by weights at the other end thereof.

28. (Original) The process according to claim 27, wherein the biocompatible polymer is selected from: nylon, cellulose, polyacrylate, polyester or viscose, their derivatives or mixture thereof.

29. (Original) The process according to claim 28, wherein said polymer is nylon.

30. (Previously Presented) The process according to claim 28, wherein said polymer is a non woven fabric.

31. (Original) The process according to claim 27, wherein the linker is selected from the group consisting of: $\text{CH}_2\text{-CH}_2\text{-SO}_2\text{-CH}_2\text{-CH}_2\text{-NH-(CH}_2)_4\text{-N=CH-(CH}_2)_3\text{-CH=O}$ or a peptide comprising a diamino-monocarboxylic amino acid or a monoamino-dicarboxylic amino acid.

32. (Original) The process according to claim 31, wherein the diamino-monocarboxylic amino acid is chosen between arginine and lysine and the monoamino-dicarboxylic amino acid is chosen between glutamic acid and aspartic acid.

33. (Original) The process according to claim 27, wherein said contaminants are selected from the group consisting of: parasiticides, weed killers, pesticides, drugs and metabolites thereof, hormones and metabolites thereof, wine malolactic fermentation products, and toxins.

34. (Original) The process according to claim 33, wherein said contaminants are further selected from the group consisting of: atrazine, aflatoxin, ochratoxin, fumonisine, cadaverine, putrescine, urethane, progesterone and salmonella antigen.

35. (Original) The process according to claim 27, wherein said membranes are kept immersed in the liquid for a time from 1 to 24 hours.

36. (Original) The process according to claim 27, wherein said membranes are kept immersed in the liquid for a time from 1 to 6 hours.

37. (Currently Amended) The process according to claim 27, which is performed without with stirring.

38. (Original) The process according to claim 27, wherein said food liquid is selected from the group consisting of: wine, milk, fruit juice, vegetable juice, beer and water.

39. (Original) The process according to claim 27, wherein said antibodies are polyclonal antibodies.

40. (Original) The process according to claim 27, wherein the total surface of the membrane/s for contaminant is such that the molar ratio of the immobilized antibody to the contaminant toward which the antibody is directed is ≥ 1 .

41. (Original) The process according to claim 40, wherein the said molar ratio is from 1 to 5.

42. (Original) The process according to claim 41, wherein said molar ratio is from 1 to 2.

43. (New) The process according to claim 27, which is performed in a single operation.

REMARKS

Rejection of Claims 27-42 under 35 USC 103(a) as being unpatentable over Kopf (US 6,139,746 incorporating the disclosure of US 5,868,930) in view of Weimer (US 5,998,222) and Baeumner (US 6,576,460)

Claim 27 has been amended by introducing a technical feature concerning the one or more membranes (according to paragraphs [0027] and [0169] of the pending description). Claim 37 has been amended by introducing a process condition (according to paragraph [0027] of the pending description) and claim 43 has been added, while setting forth a further process limitation (according to paragraph [0042] of the pending description).

The Kopf patent, US 6,139,746 discloses a process for purifying liquid foods, that employs a combination of one or more types of chromatography resins and one or more cross-flow filters, that are effected in sequential chromatographic and diafiltration separation steps in a cross-flow filtration system (column 3, lines 17-21).

Particularly, the cross-flow filter modules and cross-flow filter cassettes deemed to be useful for such a filtration step are commercially available and even described in the US patents cited at column 9, lines 50-62, while including US 5,868,930 of Kopf.

The cited patent relates to filtration cassettes, of a type comprising membrane filter sheets arranged in a multilaminate, peripherally bonded array, wherein the filter sheets alternate with permeate sheet elements, and retentate channel elements. Particularly, the resulting multilaminate, as shown for example in Fig. 18 in an exploded elevation, has the filter sheets, that can be made of different types, such as a retentate sheet, filter sheet and permeate sheet (column 10, lines 24-31), and end plates made of stainless steel or other suitable metal, polymers, such as polypropylene or polysulphone (column 15, lines 57-61). Further in the description at

column 23, lines 62-67, and even in claim 4, it is disclosed that sheet members are inter-bonded by techniques including heat bonding, ultrasonic bonding, radio frequency bonding, microwave bonding, adhesive bonding, etc., that are then stacked in the final filtration cassette. As more clearly illustrated by Figures 1 and 2, the sheet members are fastened and contained therein and are expressly prevented from any movement.

Therefore, the claimed process for decontaminating a liquid food, wherein one or more membranes are free to move in the liquid, is clearly different from the process disclosed in the Kopfs patents which teach that the purification of liquid food needs a sequential chromatographic step and diafiltration separation step, the latter being in a cross-flow filtration system where filter sheet members are fastened and contained therein.

Furthermore, the complexity and the technical features of this prior art process makes the Applicant's process even non-obvious since there is no motivation to modify such a previous process in the direction of the current invention. On the contrary, the Kopf patents teach away from the Applicant's process as Kopf discloses a filtration process, whose efficiency depends on the firmness and on the fixing of the multilaminate between the two end plates made of stainless steel.

The process of the current invention provides an unexpected result not demonstrated in the prior art patents. It was unexpected that one or more membranes let free to move in the liquid, therefore, being only immersed therein, but without any filtration step, could be able to efficiently decontaminate the liquid itself. In fact, in the process according to the current invention, the one or more membranes are not tightened, like in the filtration systems where a pressure of the passing-through liquid must be resisted. In contrast, the one or more membranes of the current process are only kept taut by floats at one end and by weights at the other end, in

order to expose the widest possible surface of said one or more membranes to the liquid, thus maximizing the decontamination deriving from the contact between the antibodies linked thereon and the contaminants dissolved in the liquid itself. Therefore, for this reason, the membranes of the current invention are not fixed but are free to move in the liquid.

As far as the Weimer's patent US 5,998,222 is concerned, it is disclosed the removal of contaminants from milk and other liquids by sorption to antibodies, specific for said contaminants, chemically conjugated and linked to sorption beads (as remarked at page 3, lines 13-15 of the outstanding Office Action). The Applicant has already discussed the use of beads as substrates for decontaminating the liquids. In fact, in the prior art section of the current application, particularly at paragraphs [0013] to [0017], the Application noticed that "some drawbacks are inherent in the industrial application of said technique:

- a. the microspheres (i.e. beads) used as a means of immobilization and utilization of decontaminants, are precipitable. Therefore, the food liquid must be vigorously stirred. It follows that the process, which, moreover, is not always technically applicable, involves considerable modification costs;
- b. since the surface of contact with the liquid to be decontaminated is small; the decontamination time is relatively long and not always compatible with the production processes;
- c. since the antibody is bound to the solid support by adhesion, i.e. through a weak bond; it tends to be detached there from in considerable amounts during the washing and reactivation steps, carried out to allow its use in successive processes. It follows that it cannot be reused as many times as needed not to significantly affect the production costs;
- d. the liquid filtration required at the end of the process determines an increase in production times and costs."

For these reasons, a skilled person would have never considered this document for improving the decontamination of liquids, as no suggestions for overcoming the above drawbacks have been recognized in the Weimer's patent. Additionally, The Background section specifically teaches away from the use of beads as disclosed in the Weimer patent. Thus, accordingly, the skilled person would not combine the Weimer patent with the Kopf's patents, since the implementation of two processes respectively disclosed are incompatible with each other.

As far as the Baeumner's patent US 5,576,460 is concerned, it is described as "a filtration-detection device for detecting or quantifying an analyte in a test sample. The filtration-detection device includes a filtration device having a first binding material immobilized thereto, wherein the first binding material is capable of binding to a portion of the analyte, and a detection assembly positioned relative to the filtration device to detect or quantify analyte bound to the first binding material" (column 1, line 62, to column 2, line 2). With reference to Figure 16, it is disclosed that a "membrane (20) rests on top of the membrane holder (22) which in turn rests on top of the membrane holder support (28) region of the outer housing (10). The outer housing (10) has an inlet hole (26) that allows insertion of a pipette tip (24) for the application of test mixture, liposome lysing agents, buffers, and the like into the filtration device. Material that is not retained on the membrane (20) passes through an outlet (12) and is collected from the liquid outlet (14)" (column 8, lines 47-55).

This document is therefore not relevant prior art as refers to a filtration-detection device for analytical purposes only. As a matter of fact, said device shows an inlet hole that allows insertion of a pipette tip, thus meaning that only very little amount of contaminated liquid can be processed in the disclosed device, as also confirmed by the Example 18, where all the amounts

considered are in the order of μL . Furthermore, “the filtration-detection device includes a filtration device having a first binding material immobilized thereto, wherein the first binding material is capable of binding to a portion of the analyte, and a detection assembly positioned relative to the filtration device to detect or quantify analyte bound to the first binding material” (column 4, lines 42-47). This shows that the object of the Baeumner’s patent is to separate the pre-determined analyte from the liquid in order to detect it or quantify the same in the test sample, but this doesn’t mean that the liquid collected from the device outlet, independently from the liquid amount involved, is “safer for human consumption and poses fewer health risks” as supposed at page 4, lines 1-2 of the outstanding Office Action. In other words, this doesn’t mean that the out flowing liquid is suitably depleted from all the contaminants.

Therefore, the skilled person would have never considered this document for improving the decontamination of liquids, as the result achieved by the Baeumner’s patent is to separate an analyte in a purest possible condition for the analytical characterization, not to make the remaining liquid decontaminated from the contaminants contained therein.

Accordingly, the skilled person would not combine the Baeumner patent with the Kopf patents, both of which refer to filtration processes that include a membrane that is fixed or connected to a housing. In fact, a hypothetical application of the Kopf’s teaching to the Baeumner’s device could only result in a more efficient analyte-detection system that employs a chromatographic column before a filtration device for detecting or quantifying an analyte in a test sample. This could only improve the separation/purification of analyte/s in view of their analytical characterization, which would not be concerned with the quality of the discharged liquid. Therefore, the combination of Kopf and Baeumner does not teach the limitations disclosed in amended claim 27.

To establish prima facie obviousness all the claim limitations must be taught or suggested by the prior art. (see MPEP section 2143.03) As there is no disclosure in the combined references of immersing a membrane having antibodies chemically conjugated through a linker specific for removal of contaminants into a liquid food to remove the contaminants wherein the membranes are free to move in the liquid and being kept taut by floats at one end and by weights at the other end thereof., applicant's attorney respectfully requests withdrawal of the rejection.

Conclusion

In view of the above amendment, applicant believes the pending application is in condition for allowance. The Examiner is invited to telephone the undersigned attorney if doing so would advance prosecution of this case.

Dated: November 11, 2008

Respectfully submitted,

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